Infant Flow® SiPAP Plus user guide

CareFusion

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Section 1: Circuit setup

WARNING:

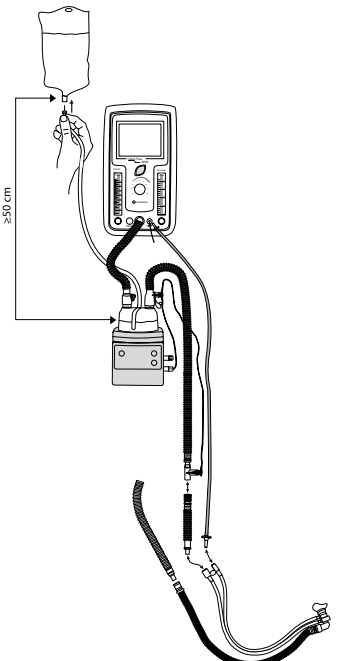
- Do not attach generator to patient until verification and initial setup are complete

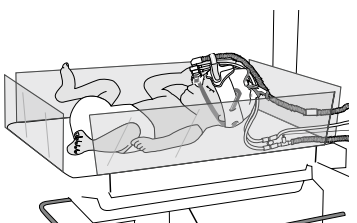
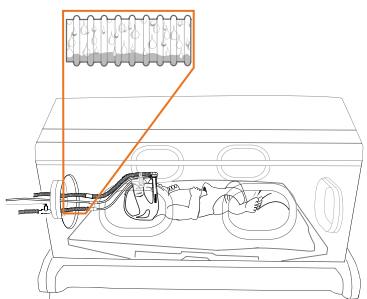
CAUTION:

- Follow manufacturer's instructions for setup and operation of humidifier

OPTIONAL:

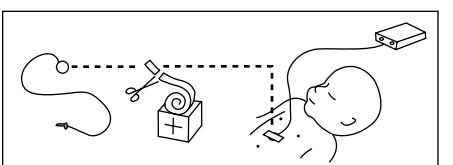
- Use transducer interface for Apnea and Low Breath Rate alarm, and BiPhasic Tr mode (Intl only)



Open bed or crib	Isolette
	Use extension tube with isolette. Remove extension tube if excessive condensation occurs. 

Abdominal sensor placement

1. Connect transducer to driver.
2. Connect respiratory sensor to transducer.
3. Compress the sensor gently; LED on the transducer illuminates.
4. Apply the sensor to the infant:
   a. Pressure line perpendicular to tape.
   b. Place between the umbilicus and xiphisternum.
   c. Alternative placement—the side of the abdomen.



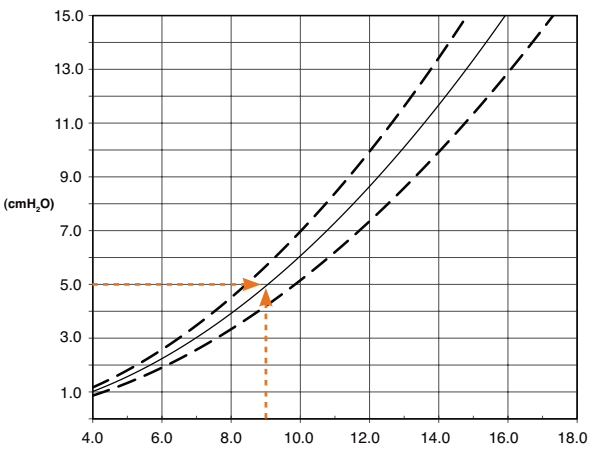
5. Verify correct placement. Transducer LED illuminates on expiration, and front panel LED on inspiration.

OPTIONAL:

- Use transducer interface for Apnea and Low Breath Rate alarm, and BiPhasic Tr mode (Intl only)

Pressure Nomogram for Infant Flow system

The Infant Flow SiPAP system is subject to a direct relationship between the controlled gas flow and airway pressure. For example, 8 to 9 LPM gas flow provides approximately 5 cmH_2O.



Alarm test

WARNING:

Prior to patient application, ensure that all User Verification testing and calibration procedures are successfully completed. User Verification testing and calibration procedures must be done off patient.

1. Connect air and oxygen gas supply. Connect power cord to AC outlet. Attach patient circuit, generator and patient interface. Occlude the opening to the patient.
2. Power up the driver and allow Power On Check to complete.
3. From nCPAP mode, with alarms set, remove occlusion from opening to patient. Low pressure alarm activates. Restore the occlusion and rest the alarms.

Alarm test initial settings	
Air supply	> 30 psig (2.1 bar)
N/A	High
Infant Flow LP generator/circuit	
nCPAP/Press low	9 LPM
$\%O_2$	30%
Press high flow	3 LPM
Mode	nCPAP
Use settings below for step 9	
Rate	30 bpm
Ti	0.3 sec
Apnea/LBR interval	20 sec

Alarm test *(continued)*

4. Adjust the nCPAP/Pres Low flow meter to 11 LPM. The high airway pressure alarm activates. Decrease flow to 8 LPM. Reset the alarms.
5. Adjust the $\%O_2$ control to 35%. The High $\%O_2$ alarm activates. Return the O_2 setting to 30%. Reset alarms.
6. Adjust the $\%O_2$ to 25%. The Low $\%O_2$ alarm activates. Return the O_2 setting to 30%. Reset the alarms.
7. Disconnect the AC power cord from the wall outlet. The Loss AC alarm activates. Reconnect the AC power cord. Reset alarms.
8. Occlude exhalation line and increase nCPAP pressure to 11 cmH_2O. The High Circuit Pressure alarm activates. Decrease flow to 8 LPM and reset alarms.
9. Select and confirm BiPhasic mode. Change the mandatory rate control setting to 1. Low Breath rate alarm activates after the default interval of 20 seconds. Return to rate of 30. Reset the alarms.

Two point oxygen calibration

1. Adjust flow meters and turn on driver.
2. Press the calibration **(CAL)** button in the Setup screen.
3. Adjust the Oxygen Control to 21%:
   a. Allow reading to stabilize.
   b. Press the flashing button to confirm.
   c. A check mark appears and $\%O_2$ display should read 21%.
4. Adjust the Oxygen Control to 100%:
   a. Allow reading to stabilize.
   b. Press the flashing button to confirm.
   c. A check mark appears and $\%O_2$ display should read 21%.
5. Press **Exit** button.

Two point oxygen calibration *(continued)*

NOTE:

- If calibration fails, a red "X" is displayed, the alarm sounds and an Error code is displayed; repeat the calibration procedure
- Two point calibrations are required with initial setup and circuit changes

Disable oxygen sensor

Disable O_2 button

1. From **Setup screen**, press the calibration **(CAL)** button.
2. Press the **O_2 Disable** button:
   a. Oxygen monitoring and the audible oxygen alarms are disabled.
   b. Error Code 55 is displayed.
3. Use an external oxygen analyzer to monitor FiO_2.

WARNING

- Always use an external oxygen monitor if the oxygen sensor is disabled.

Startup menu and leak test

1. Connect prong or mask to generator; occlude opening to patient.
2. Set nCPAP flow to 9 LPM and High flow to 3 LPM.
3. Turn on the driver.
4. Verify measured pressure is 5 ±1%. If less than 5 cmH_2O is displayed check for leaks.
5. Touch flashing icon to confirm.
6. Adjust O_2% dial to desired setting. Verify measured value is within +/- 3%.
7. Touch flashing icon to confirm.

Startup menu and leak test *(continued)*

8. Adjust press High flow as desired.
9. Touch flashing icon to confirm.
10. Connect transducer assembly to the traducer interface connector on the front of the Infant Flow SiPAP, if desired. Touch flashing icon to confirm.
11. Touch **NCPAP** or **Alarm Mute/Reset** button to set alarms.
12. Measured CPAP should be 5 cmH_2O. If not, check for leaks.
13. Remove occlusion to prongs or mask. Measured CPAP should drop to 0 to 2 cmH_2O. If not, check for occlusions.

Section 2: Operation

A. Power LED

B. Alarm warning bar

C. Transducer interface LED

D. LCD touch screen

E. $\%O_2$ control

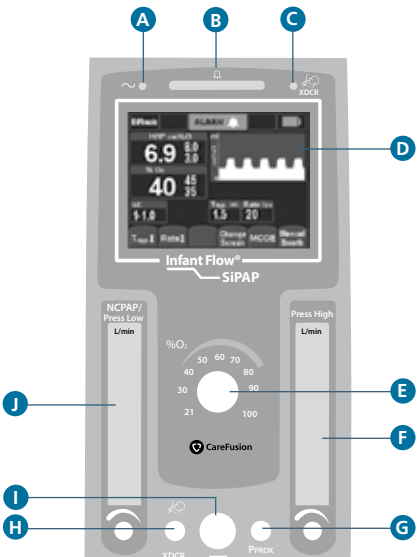
F. Press high flow meter

G. Connection proximal pressure line

H. Transducer interface connection

I. Circuit connection inspiratory limb

J. nCPAP/pres low flow meter



Soft key operation

Description	Example
A button that is enabled.	
A button that is inhibited due to non-availability of the designated feature or pending acknowledgement of an active alarm condition.	
A selected mode or control pending confirmation is visually highlighted and intermittently flashes between yellow and white text.	
While a button is pressed, the edges are highlighted to provide a pressed appearance.	

Soft key operation *(continued)*

Description	Example
When there is an active alarm associated with a measured value, the measured value concerned is displayed with RED FLASHING text. The associated limit value (if any) is displayed in RED.	
When an alarm that is associated with a measured value is resolved, the device remains in a LOW priority alarm state, with the measured value displayed in YELLOW FLASHING text and the associated limit displayed in YELLOW, until the alarms are cleared by the operator.	
Manual breath delivers a Biphasic cycle at current settings for T-High, Press High and $\%O_2$. Only one BiPhasic cycle is delivered regardless of button press duration.	
If no screen interactions occur for a period of 120 seconds and there are no active alarms, the screen goes to a "locked" state to prevent inadvertent entries. To unlock the screen, press the lock icon.	

Operational modes

CPAP is a constant single level of positive pressure to the infant's airway, facilitating the restoration of functional residual capacity and correction of hypoxemia.

BiPhasic is two levels of pressures, delivered at a set Time High (T-High) criteria, rate and pressure settings. Small incremental pressure increases of 2 to 3 cmH_2O augment functional residual capacity and may off load work of breathing.

Low breath rate **(LBR)** detection is via a respiratory abdominal sensor. The LBR alarm will be triggered when the set time interval is exceeded. If the infant's breath is detected within the next time out period, the alarm will silence.

Alarm set/confirm screen

1. Touch the nCPAP or Alarm button for 3 seconds to set the alarm limits. If neither button is not touched within 2 minutes, the alarm limits will automatically be set.

2. The screen will change to Mode Select screen with the driver operating in nCPAP mode.

Mode Select screen

1. Press the desired mode button. The display will change to the Parameter Adjust screen.

NOTE:

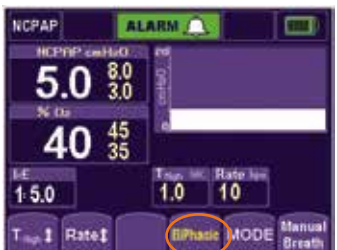
- Only the available modes will be displayed on the menu bar
- For Low Breath Rate (LBR) modes, attach the transducer assembly and respiratory abdominal sensor

Parameter Adjust screen

1. Press the desired parameter button to change. Only the relevant controls are visible. The selected parameter and associated numeric display are highlighted.
2. Use the up and down arrow buttons to adjust the setting.
3. Confirm the change by pressing the parameter button. If no action is taken, the new parameter will take effect after 15 seconds.

NOTE:

- Parameter changes can be made during initial setup and normal operation



Incompatible settings

- When one parameter **(A)** change is incompatible with another parameter **(B)**, the software will automatically make an adjustment to that parameter **(B)**
- If the adjusted parameter **(A)** is restored in less than 15 seconds, the parameter **(B)** change is reversed
- When parameter adjustments cause a reduction in another parameter to maintain requirements for minimum breath interval, the reduced parameter is displayed in RED for 15 seconds

EXAMPLE:

- BiPhasic mode with T-High = 2.0 seconds: As rate is increased above 28 breaths per minute, the constraint on minimum T-Low requires a reduction in T-High. If rate is increased to 29, then T-High will automatically reduce to 1.9 seconds. If rate is reduced back to 28 within 15 seconds, the previous T-High setting (2.0 sec) is restored.

NOTE:

- T-High automatically reduces to maintain a minimum T-Low of 100 milliseconds.

Main screen

- The **Main screen** displays current mode of operation alarm status, battery charge status, monitored parameters and pressure time graphic display
- Only the active parameters for the selected mode are available for adjustment
- Press the **Change Screen** button to access the Monitored Parameter screen

Monitored Parameter screen

1. The Monitored Parameter screen displays measured values and parameter settings for all BiPhasic modes.
2. Active parameters are available for adjustment.
3. Press the **Change Screen** button to return to the Main screen.

Alarm management

Audible alarm priority

- *High priority*: A series of 10 tones every 10 seconds, flashing red
- *Medium priority*: Three audible tones every 15 seconds, flashing yellow
- *Low priority*: Two audible tones every 30 seconds, solid yellow

Silencing audible alarms

Pressing the **Alarm Reset** button will silence active alarms for up to 30 seconds. A new high priority alarm condition will cancel the alarm silence.

Resetting alarms

Press the **Alarm Reset** button for 3 seconds to clear resolved and low priority alarm and to rest alarm limits.

Final check and routine inspection

Inspect the system at least every 3 to 4 hours to:

- Ensure the patient is receiving the prescribed level of CPAP
- Ensure the generator is stable, secure and not pulling upward on the nose
- Check for deformation or irritation to the nose or surrounding tissue
- Ensure the patient's septum is clearly visible when using prongs
- Ensure the patient's eyes are clearly visible and the nares are not blocked, when using masks
- Inspect the fixation device and straps for proper tension and adjust as needed to maintain a proper fit
- Monitor the patient for gastric insufflation and abdominal distension
- Monitor for excessive condensation in circuit and generator

Troubleshooting

Alarm	Priority	Possible cause	Potential actions
$\%O_2 < 18\%$	High	O_2 CAL required	Reset FiO_2 above limit, O_2 CAL
$\%O_2 < 104\%$	High	O_2 CAL required	Reset FiO_2 below limit, O_2 CAL
High $\%O_2$	High	$\%O_2$ setting changed, supply gas failure, water trap overflow	Correct FiO_2, reset alarm limits
Low $\%O_2$	High	Blender setting changed, supply gas failure, water trap overflow	Correct FiO_2, reset alarm limits
Over pressure	High	Flow Rate set too high, occlusion of exhalation limb, blocked silencer/filter	Check exhaust tube/filter, reduce flow rate, reset alarm limits
Low battery	Warning	Battery charge status change	Connect to AC
Low battery voltage	Medium	Battery disconnect, fails to hold charge	Connect to AC
Loss AC	High	AC power disconnected	Connect to AC
High nCPAP/ Press Low	High	Setting change, circuit disconnect	Reset alarm limits
Low nCPAP/ Press Low	High	Setting change, circuit disconnect, leak	Reset alarm limits, check for leaks
High BiPhasic pressure	High	Press High setting change, circuit disconnect	Reset alarm limits

Notes

⚠ **WARNING**—U.S. Federal Law restricts this device to sale by or on the order of a physician.

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